

10/588295  
IAP11 Rec'd PCT/PTO 04 AUG 2006

PATENT Case No. 21502P

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Chartrain, Michel; Bentley, Laura Kizer;  
Krulwicz, Barbara Ann; Listner, Kristin M.; Sun,  
Wen-jun; Lee, Chanyong Brian

Serial No. To be assigned

Filed: Herewith

For: PROCESS FOR LARGE SCALE PRODUCTION OF  
PLASMID DNA BY E. COLI FERMENTATION

Art Unit: To be assigned

Examiner: To be assigned

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

INFORMATION DISCLOSURE STATEMENT  
UNDER 37 CFR 1.97

Sir:

1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
4. Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

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**INFORMATION DISCLOSURE STATEMENT**  
 PATENT Case No. 21502P

5. Pursuant to 37 C.F.R. 1.98(d), copies of references listed on the attached form that were submitted to or cited by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

RELATED APPLICATION		
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE

If this is inconvenient, additional copies will be submitted upon request.

6. In accordance with 37 C.F.R. 1.97, (check one)

- ☒ the attached information is filed within three months of the filing date of the captioned case.
- ☐ the attached information is filed more than three months after the filing date but prior to the mailing of a first Office Action on the merits.
- ☐ the attached information is filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- ☐ the attached information is being filed more than three months after the filing date and after the mailing of a first Office Action on the merits, but before the mailing date of a Final Action, Notice of Allowance, or an action that otherwise closes prosecution in the application. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).
- ☐ each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart application *and this communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of the information disclosure statement.*
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of this Statement.

Respectfully submitted,

*Laura M. Ginkel*

By: Laura M. Ginkel

Attorney \_\_\_\_\_ For Applicant(s)

Reg. No. 51,737

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-1932

Date: August 4, 2006

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**COMPLETE IF KNOWN**

## STATEMENT BY APPLICANT

*(use as many sheets as necessary)*

**To be assigned**

Herewith

Chartrain, Michel

**To be assigned**

**To be assigned**

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of

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Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO

# INFORMATION DISCLOSURE

## STATEMENT BY APPLICANT

(use as many sheets as necessary)

Application Number	To be assigned
Filing Date	Herewith
First Named Inventor	Chartrain, Michel
Group Art Unit	To be assigned
Examiner Name	To be assigned
Attorney Docket Number	21502P

Sheet	2	of	3
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### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	A	CHEN, W., ET AL., Journal of Industrial Microbiology & Biotechnology, "Automated fed-batch fermentation with feed-back controls based on dissolved oxygen (DO) and pH for production of DNA vaccines", Vol. 18, pages 43-48, 1997.
	B	ELY, SUSAN, ET AL., Mol. Gen Genet, "Regulation of plasmid DNA synthesis: Isolation and characterization of copy number mutants of miniR6-5 and miniF plasmids", Vol. 181, pages 29-35, 1981.
	C	KORZ, D.J., ET AL., Journal of Biotechnology, "Simple fed-batch technique for high cell density cultivation of <i>Escherichia coli</i> ", Vol. 39, pages 59-65, 1995.
	D	LAHIJANI, ET AL., Human Gene Therapy, "High-yield production of pBR322-derived plasmids intended for human gene therapy by employing a temperature-controllable point mutation", Vol. 7, pages 1971-1980, 1996.
	E	LEE, SANG YUP, TIBTECH, "High cell-density culture of <i>Escherichia coli</i> ", Vol. 14, pages 98-105, 1996.
	F	PRATHER, KRISTALA JONES, ET AL., Enzyme and Microbial Technology, "Industrial scale production of plasmid DNA for vaccine and gene therapy: plasmid design, production, and purification", Vol. 33, pages 865-883, 2003.
	G	NAMDEV, PRADYUMNA K., ET AL., Biotechnology and Bioengineering, "Effect of oxygen fluctuations on Recombinant <i>Escherichia coli</i> Fermentation", Vol. 41, pages 666-670, 1993
	H	O'KENNEDY, R.D., ET AL., Journal of Biotechnology, "Effects of growth medium selection on plasmid DNA production and initial processing steps", Vol. 76, pages 175-183, 2000.
	I	O'KENNEDY, ET AL., Biotechnol. Appl. Biochem. "Effects of fermentation strategy on the characteristics of plasmid DNA production", Vol. 37, pages 83-90, 2003.
	J	PRAZERES, DUARTE M. F., ET AL., TIBTECH, "Large-scale production of pharmaceutical-grade plasmid DNA for gene therapy: problems and bottlenecks", Vol. 17, pages 169-174, 1999.
	K	REINIKAINEN, P., ET AL., Biotechnology Letters, " <i>Escherichia coli</i> growth and plasmid copy numbers in continuous cultivations", Vol. 11, No. 4, pages 225-230, 1989.
	L	REINIKAINEN, P., ET AL., Biotechnology and Bioengineering, " <i>Escherichia coli</i> plasmid production in fermenter", Vol. 33, pages 386-393, 1989.
	M	RIESENBERG, D., ET AL., Journal of Biotechnology, "High cell density cultivation of <i>Escherichia coli</i> at controlled specific growth rate", Vol. 20, pages 17-28, 1991.
	N	RIESENBERG, D. ET AL., Current Opinion in Biotechnology, "High-cell-density cultivation of <i>Escherichia coli</i> ", Vol. 2, No.: 3, pages 380-384, 1991.
	O	SEO, JIN-HO, ET AL., Biotechnology and Bioengineering, "Continuous cultivation of recombinant <i>Escherichia coli</i> : existence of an optimum dilution rate for maximum plasmid and gene product concentration", Vol. XXVIII, pages 1590-1594, 1986.

Examiner Signature	Date Considered
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Application Number To be assigned

Filing Date

Herewith

First Named Inventor

Chartrain, Michel

Group Art Unit

To be assigned

Examiner Name

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Sheet

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of

3

Attorney Docket Number

21502P

### NON PATENT LITERATURE DOCUMENTS

Examiner  
Initials\*

Cite  
No.

Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.

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WANG, ZHIJUN, ET AL., Process Biochemistry, "Medium design for plasmid DNA production based on stoichiometric model", Vol. 36, pages 1085-1093, 2001.

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YEE, L., ET AL., Biotechnology, "Recombinant protein expression in high cell density fed-batch cultures of *Escherichia coli*", Vol. 10, pages 1150-1556, 1992.

R

ZHANG, J., ET AL., Appl. Microbiol. Biotechnology, "Chemically defined media for commercial fermentations", Vol. 51, pages 407-421, 1999.

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